

REMARKS

This Amendment is in response to the final Office action (Paper No. 20080614) mailed on 20 June 2008. Reexamination and reconsideration are respectfully requested.

Listing of The Claims

Pursuant to 37 CFR §121(c), the claim listing, including the text of the claims, will serve to replace all prior versions of the claims, in the application.

Status of The Claims

Claims 7, 13, and 19 are pending in this application.

Amendment of The claims

Claims 7, 13 and 19 are amended, and claims 11, 17 and 24 are cancelled.

Specifically, claim 7 is amended to incorporate claim 11, and claim 11 is cancelled.

Claim 13 is amended to incorporate claim 17, and claim 17 is cancelled.

Claim 19 is amended to incorporate claim 24, and claim 24 is cancelled.

Issues raised by Paper No. 20080614

I. Response to Examiner's "Response to Argument"

Regarding Applicant's arguments filed on 26 March 2008, on page 4 of Paper No. 20080614, the Examiner stated:

"Examiner points out that Applicant has failed to provide any reason as to why an arcuate micro-pattern is preferred to the other disclosed embodiments of a micro-pattern as set forth in Applicant's own specification (i.e. a micro-pattern having a polygonal cross-section as shown by embodiments of Figures 1, 2 and 4), nor has Applicant revealed that such an

arcuate pattern solves any particular problem that cannot be solved by a pattern having a polygonal cross-section.”

Applicant respectfully disagrees because, in Applicant’s Amendment filed on 26 March 2008, Applicant explicitly explained that the arcuate micro-pattern is preferred to the polygonal micro-pattern, because the outline of the arcuate micro-pattern has a greater length than that of the polygonal micro-pattern.¹

The following is a mathematical explanation regarding the length of an arc between two points being greater than the length of a straight line between the same two point. FIG. A schematically illustrates an example of Applicant’s arcuate cross-sectional outline compared with Cuilleron’s triangular cross-sectional outline. In the figure, the combination of arcs AC and CB represents Applicant’s arcuate cross-sectional outline of the micro-patterns formed on the inclined flanks of the helical threads, while the combination of the straight lines AC and CB represents Cuilleron’s triangular cross-sectional outline of the projections formed on the threaded surface. Joined arcs AC and CB are circumscribed by a circle having a center of O and a radius of R.

The length of the arc AC is established by:

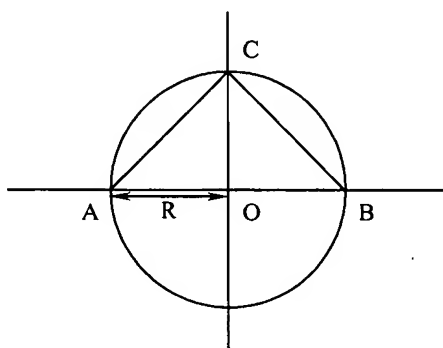
$$L_{AC} = \pi / 2 \times R \approx 1.57 \times R,$$

while the length of the straight line AC is established by:

$$AC = \sqrt{2} \times R \approx 1.41 \times R.$$

¹ On page 9 of Applicant’s Amendment filed on 26 March 2008, Applicant stated: “Applicant’s arcuate cross-sectional outline is advantages over the polygonal cross-sectional outline because arcuate cross-sectional outline has a greater length than that of the polygonal cross-sectional outline, and consequently the micro-threads having arcuate cross-sectional outlines may provide a greater surface area”.

Because $1.57 \times R$ is greater than $1.41 \times R$, the length of the arc AC is greater than the length of the straight line AC. Applicant's arcuate cross-sectional outline is longer compared with Cuilleron's triangular cross-sectional outline. Consequently, Applicant's helical implant provided with the



micro-patterns having arcuate cross-sectional outlines have a larger surface area compared with Cuilleron's anchoring threading.

FIG. A Applicant's arcuate cross-sectional outline (arc ACB) compared with the prior art's triangular cross-sectional outline ($\triangle ACB$).

As explicitly set forth in Applicant's original specification, it is desirable to increase the contact area between an helical implant and a bone in which the helical implant is implanted, to enhance the mechanical engaging force between the helical implant and the bone tissue. ² This

² Page 3, lines 25-30 of Applicant's original specification reads: "The present invention has been made to solve the above problems, and it is an object of the present invention to provide a helical implant, which is formed with a micro-pattern on thread inclines of the helical implant, so that a **contact area and a engaging force between the implant and the jaw bone can be increased**, and so that stress concentration can be restricted, thereby dispersing a physiological load."

distinction, namely “the difference between the subject matter sought to be patented and the prior art”³, is reflected in Applicant’s claim 7’s:

“the micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns”,

claim 13’s:

“each one of the recesses and protrusions having an identical arcuate cross-sectional outline throughout the entire length of the micro-patterns”,

and claim 19’s

“with said micro-pattern comprising at least one groove and at least one ridge having identical arcuate outlines and opened at one side when viewed on any cross sectional plane of the screw thread, and said cross sectional plane containing the longitudinal axis of the cylindrical core”.

Therefore, Applicant’s helical implant provided with the micro-patterns is advantageous over the Cuilleron ‘512’s implant provided with protrusions having triangular profile.

II. Claim Rejections 35 USC § 103

Claims 7, 11, 13, 17, 19 and 24 are rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Cuilleron (FR 2610512 A) in view of Hansson et al. (US 5,588,838).

II-1. Regarding claims 7, 11, 13, 17, 19 and 24, on page 3 of Paper No. 20080614, the Examiner stated:

“Additionally, although Cuilleron fails to disclose a specific distance between each micro-pattern, Hansson teaches that the distance between adjacent threads should be approximately 0.2 mm (200 µm). Therefore, it

³ 35 U.S.C. §103(a).

would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to separate each micro-pattern by 150 μm since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable values involves only routine skill in the art. In re Aller, 105 USPQ 233."

Applicant respectfully traverses.

Respectfully, the combination of Cuilleron '512 and Hansson '838 fails to teach the pending claims "distance between two adjacent micro-patterns being 150 μm ". The distance of 150 μm is critical in Applicant's invention, and cannot be discovered by mere routine experiment. On the other hand, Hansson '838 merely discloses that the distance to the adjacent microthread may be 200 μm . Hansson '838's 200 μm is different from Applicant's 150 μm by more than 30%. How can such a huge difference be discovered by mere routine experiment?

In fact, Applicant's 150 μm micro-pattern is advantageous over the Cuilleron '512 and Hansson '838's 200 μm micro-thread because the 150 μm micro-pattern provides optimal site for bone ingrowth. Particularly, in a bone system such as a Haversian system in which Haversian canals surround blood vessels, the 150 μm micro-pattern may promote bone mineralization and eventually maturation. As a consequence, the strength and speed of an osseointegration, i.e., direct structural and functional connection between the bone and the surface of the implant, will be increased.

Additionally, Applicant respectfully submits evidence to show the criticality of the distance of 150 μm between two adjacent micro-patterns. FIGS. 1-3 are histomorphometric and fluorescence microscopic photos showing animal bone growth in 150 μm micro-patterns constructed as embodiments according to the principles of Applicant's invention, at the healing time of 6 weeks.

In FIG. 1, the 150 μm micro-patterns are formed at the conical 1/3 area of the implant. Fluorescence agents such tetracycline (15mg/kg body weight, Fluka, Buchs, Switzerland), alizarin-complexon (30mg/kg body weight, Fluka, Buchs, Switzerland), calcein blue (30mg/kg body weight, Fluka, Buchs, Switzerland), were injected in the animals at 2, 4 and 6 weeks in order to show the bone growth. FIG. 1 clearly shows the bone growth into the 150 μm micro-patterns at the conical 1/3 thread of the screw implant.

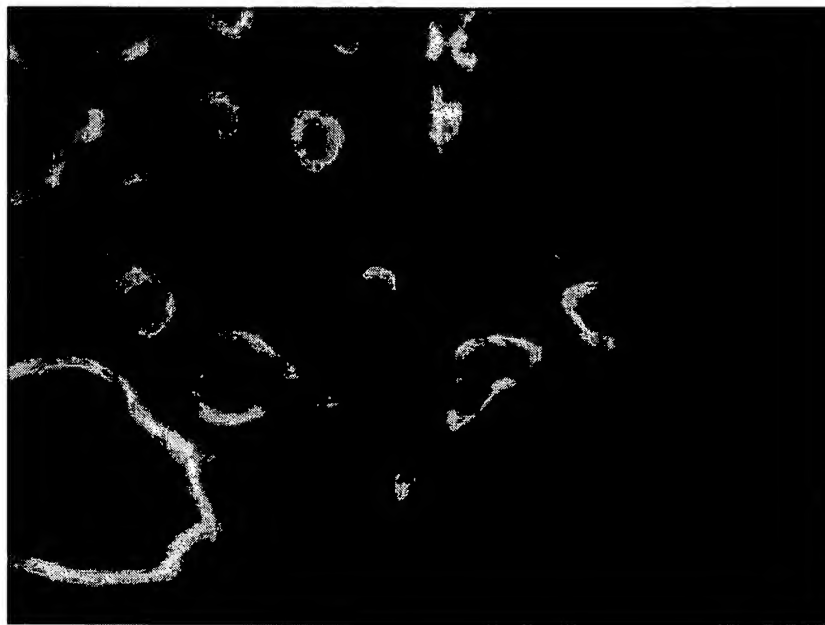


FIG. 1

In FIG. 2, the 150 μm microthreads are formed at the middle 1/3 area of the implant. FIG. 2 clearly shows the bone growth into the 150 μm micro-patterns at the middle 1/3 thread of the screw implant.

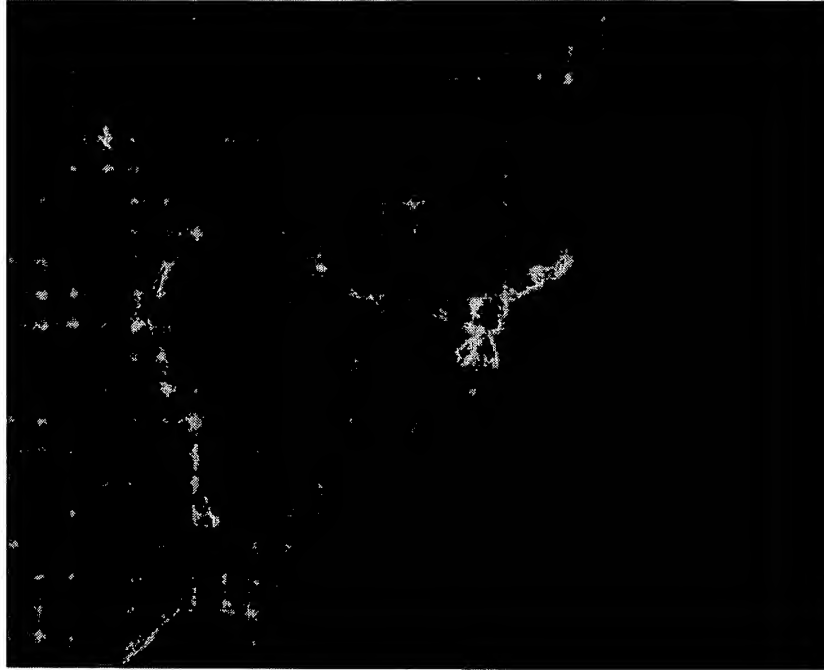


FIG. 2

In FIG. 3, the 150 μm microthreads are formed at the apical 1/3 area of the implant. FIG. 3 clearly shows the bone growth into the 150 μm micro-patterns at the apical 1/3 thread of the screw implant, where the bone tissue and microthread was surrounded with bone marrow tissue.



FIG. 3

As shown in Applicant's FIGs 1-3, after the helical implant which is formed with micro-patterns with a distance of 150 μm , is implanted into the animal bone tissue, the bone grew into the thread.

As mentioned in the MPEP §2144.05.II.A,

“Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.”

Because the pending claims' "distance between two adjacent micro-patterns being 150 μm " is critical in this invention, the combination of Cuilleron '512 and Hansson '838 fails to teach or suggests claim 7's:

"two adjacent recesses being separated by a distance on an order of 150 μm ",
claim 13's:

"two adjacent recesses being separated by a distance on an order of 150 μm ",
and claim 19's:

"the distance between the neighboring micro-patterns being 150 μm ".

Consequently, claims 7, 13 and 19 are patentably distinguishable over the prior art.

II-2. Regarding claims 7, 11, 13, 17, 19 and 24, on page 3 of Paper No. 20080614, the

Examiner stated:

"Cuilleron, however, does not explicitly disclose that said micro-patterns can be arcuate in shape. Hansson teaches an implant that utilizes a micro-pattern that have an arcuate design, whereby the spaces in between each bead are identical grooves (i.e. microbeads; column 2, lines 34-37). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to use arcuate shaped micro-patterns in the threads of Cuilleron in order to avoid, or at least minimize, stress concentrations in the bone tissue around said microthreads as taught by Hansson. Furthermore, Examiner notes that such an arcuate shape helps to avoid, or at least minimize, additional cutting into the bone of the patient during insertion, such that the patterns can be relied on instead for providing a region for bone-implant integration to occur."

Applicant respectfully traverses.

First, respectfully, Hansson '838 teaches away from forming arcuate shaped micro-patterns in the threads of Cuilleron '512, because the Examiner's proposed modification of Cuilleron '512's thread using Hansson '838's rounded microthread would make Cuilleron '512 unsatisfactory for its intended purpose, i.e., improve the anchoring of the implant. Hansson '838's alleged purpose of forming microthreads with rounded design to minimize stress concentrations around the microthreads⁴, explicitly conflicts Cuilleron '512's purpose of improving the anchoring, i.e., the engaging force, of the implant⁵. As is well known in general physics, when the stress concentration of the bone around the implant reduces, the engaging force between the bone tissue and the implant decreases, thus the anchoring of the implant deteriorates. Therefore, based on the teachings of Hansson '838, forming Hansson '838's rounded microthreads on Cuilleron '512's threads would not improve the anchoring of Cuilleron '512's implant.

As mention in the Manual of Patent Examining Procedure (MPEP) §2143.01(V),

“If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)”.

Accordingly, the Examiner's proposed modification of Cuilleron '512's thread using Hansson '838's rounded microthread would make Cuilleron '512 unsatisfactory for its intended purpose, i.e.,

⁴ Hansson '838's column 2, lines 34-37 reads: “The micro threads 9 have a rounded design in order to avoid, or at least **minimize, stress concentrations** in the bone tissues around the microthreads”.

⁵ Cuilleron '512's page 1 of EPO automated translation reads: “According to the invention, one wanted to **improve anchoring** of these elements of prostheses.....”

improve the anchoring of the implant. Therefore, Hansson '838 can not be combined with Cuilleron '512.

Secondly, the Examiner's conclusion of obviousness is based on improper hindsight reasoning using the benefit of Applicant's claimed invention. The Examiner must note that Hansson '838's microthreads are formed on the conically flaring upper portion, instead of the cylindrical main body, of the dental implant. The cylindrical main body is already formed with conventional threads to engage with the bone tissue, while the conically flaring upper portion does not have any conventional threads. There is no requirement for Hansson '838's microthreads to improve the engage force between the bone tissue and the implant.

As mention in the Manual of Patent Examining Procedure (MPEP) §2141.01(III),

“It is difficult but necessary that the decision maker forget what he or she has been taught .. about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.” *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

As discussed previously, based on Hansson '838's teaching, the rounded microthreads reduces the stress concentration of the bone around the implant. Therefore, a person with ordinary skill in the art, **at the time the present invention was made**, would not use rounded microthreads on Cuilleron '512's threads based on Hansson '838's teaching in order to avoid decreasing the stress concentration around the implant, and thus improving the anchoring of the implant in the bone tissue.

Thirdly, the Examiner has mistakenly alleged that the spaces between Hansson '838's microbeads are identical grooves. The following FIG. B is an enlarged front view of Hansson '838's implant provided with the microbeads, referring to Hansson '838's FIG. 3. As shown in FIG. B, Applicant can not find "identical grooves" either between the top layer of microbeads and the bottom layer of the spherical microbeads, or between two individual microbeads. Note that according to the Merriam-Webster Dictionary, a groove is a long narrow channel or depression. Therefore, Hansson '838 fails to teach the "identical grooves" as asserted by the Examiner.

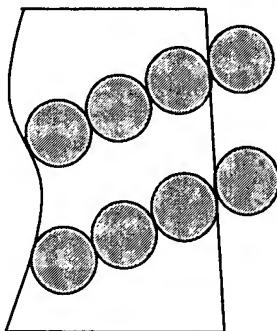


FIG. B. Hansson 838's implant provided with the microbeads.

According to the Manual of Patent Examining Procedure (MPEP) §2143.03,

To establish prima facie obviousness of a claimed invention, **all the claim limitations** must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

As discussed above, the combination of Cuilleron '512 and Hansson '838 fails to teach or suggest claim 7's:

“the micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns”,

claim 13's:

“each one of the recesses and protrusions having an identical arcuate cross-sectional outline throughout the entire length of the micro-patterns”,

and claim 19's

“with said micro-pattern comprising at least one groove and at least one ridge having identical arcuate outlines and opened at one side when viewed on any cross sectional plane of the screw thread, and said cross sectional plane containing the longitudinal axis of the cylindrical core”.

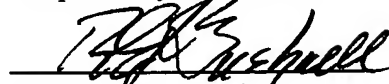
The combination of Cuilleron '512 and Hansson '838 fails to teach or suggest all of the claim limitations in claims 7, 13 and 19.

Withdrawal of the rejections of claims 7, 13 and 19, and the dependent claims thereof, is respectfully requested.

In view of the foregoing amendments and remarks, all claims are deemed to be allowable and this application is believed to be in condition to be passed to issue. Should any questions remain unsolved, the Examiner is respectfully requested to telephone Applicant's undersigned attorney.

No fee is incurred by this Amendment.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Robert E. Bushnell", is written over a horizontal line.

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